

Remarks

Claims 1, 10, 12, 14-15, 17-20, and 21-74 will be pending upon entry of this amendment. Claims 27-29, 32, 35, 40, 42, 47-50, 53, 57, 62, 65, 66, 68, and 73 have been amended. The amendments are fully supported by the specification and original claims and do not introduce any new matter. Claims 21-26 and 30-31 were previously allowed. Claims 1, 10, 12, 14-15, 17-20, 33-34 and 54-56 were withdrawn from further consideration by the Examiner.

Applicants note that withdrawn claims 33-34 and 54-56 are directed to group XI which encompasses methods of detecting ICE LAP-6 using the antibodies of Group IV. In light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. See 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

...in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, should the claims of group IV be allowed, Applicants request that claims 33-34 and 54-56 be rejoined and examined for patentability. See also M.P.E.P. § 821.04.

I. Explanation of Extra Claim Fees

The instant Response and Amendment Under 37 C.F.R. 1.111 has 63 total claims and 8 independent claims. Applicants' previous communication, Election with Traverse Under 37 C.F.R. § 1.143 and Second Preliminary Amendment, filed August 4, 2003, also listed 63 total claims and 8 independent claims. However, due to a clerical error, Applicants mistakenly indicated 43 total claims on the Fee transmittal filed August 4, 2003. Applicants note that the Fee Transmittal submitted herewith authorizes payment for the 20 extra claims inadvertently omitted from the Fee Transmittal of August 4, 2003.

II. Amendments to the Specification and Claims 42 and 57 Concerning the ATCC Deposit Number:

The specification has been amended to refer to the 1095150 human ICE LAP-6

cDNA of the present application by its American Type Culture Collection (ATCC) designation, ATCC Deposit Number 97590. Applicants assert that Human Genome Sciences, Inc. deposited two clones with ATCC on May 30, 1996, DNA plasmids 1290857 and 1095150. The 1095150 cDNA plasmid of the present application was given ATCC designation 97590, as shown in the ATCC deposit receipt submitted herewith as Exhibit A. Furthermore, Applicants have amended claims 42 and 57 to refer to "ATCC Deposit Number 97590" instead of "ATCC Deposit Number 1095150." This amendment is also supported by Exhibit A, as described above. Thus, no new matter has been added by way of these amendments to the specification, and claims 42 and 57.

III. Rejection of Claims 42-53 and 57-63 Under 35 U.S.C. § 112, First Paragraph

Claims 42-53 and 57-63 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description because insufficient assurance has been provided that all of the conditions of 37 CFR sections 1.801 through 1.809 have been met for the deposited cDNA clone. *See* page 3, 4th full paragraph of the present office action. The rejection is respectfully traversed.

While Applicants believe that the instant specification provides adequate assurances that the terms of the Budapest Treaty have been met, a Statement Concerning the Deposited cDNA Clone, signed by Applicants' attorney, is enclosed. In view of the enclosed Statement regarding availability of the deposited clone, Applicants believe the Examiner's concerns have been fully addressed. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

IV. Rejection of Claims 68-74 Under 35 U.S.C. § 112, First Paragraph for Enablement

Claims 68-74 are rejected under 35 U.S.C. § 112, first paragraph, because the claimed invention is allegedly not enabled by the specification. *See* page 4, first full paragraph of the present office action. In particular, the Examiner has rejected claims 68-74 because they allegedly recite "comprising" in such a way that the claims are "open-ended." The Examiner states:

The specification does not provide *any* guidance as how to make and use *any* isolated antibody or fragment thereof obtained from an animal that has been immunized with *any* protein an amino acid sequence such as the amino acid

sequence of amino acid residues 10 to 20, 40 to 50, 70 to 90 or 100 to 113 of SEQ ID NO:1 because the term "comprising" is open-ended. It expands the amino acid residues mentioned above to include additional amino acids at either or both ends.

Page 5, second full paragraph of the present office action (emphasis in the original). Applicants respectfully disagree; however, Applicants have amended claim 68 to substitute "consisting of" for "comprising." Applicants assert that the specification enables one skilled in the antibody arts to make and use the invention of claim 68, and dependent claims 69-74. Thus, Applicants respectfully request that rejection of claims 68-74, under 35 U.S.C. § 112, First Paragraph, be withdrawn.

V. Rejection of Claims 68-74 Under 35 U.S.C. § 112, First Paragraph for Written Description

Claims 68-74 are rejected under 35 U.S.C. § 112, first paragraph, because the claimed invention allegedly lacks written description. *See* page 6, third full paragraph of the present office action. In particular, the Examiner has rejected claims 68-74 because they allegedly recite "comprising" in such a way that the claims are "open-ended." The Examiner states:

...there is inadequate written description about the structure associated with functions of any protein "comprising" an amino acid sequence of amino acid residues such as 10 to 20, 40 to 50, 70 to 90 or 100 to 113 of SEQ ID NO: 1 because the term "comprising" is open-ended. It expands the amino acid residues mentioned above to include additional amino acids at either or both ends. There is inadequate written description about the undisclosed amino acid residues to be added, much less about the binding specificity of the claimed antibody.

Page 7, second full paragraph of the present office action. Applicants respectfully disagree; however, as noted in the previous section, claim 68 has been amended. Applicants respectfully submit that the specification describes the subject matter of claims 68-74 in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Thus, Applicants respectfully request that rejection of claims 68-74, as allegedly lacking written description under 35 U.S.C. § 112, First Paragraph, be withdrawn.

VI. Rejection of Claims 68-74 Under 35 U.S.C. § 112, First Paragraph for Written Description, New Matter

Claims 68-74 are rejected under 35 U.S.C. § 112, first paragraph, because claim 68 allegedly introduces new matter to the present application and therefore lacks written description. *See* page 8, second full paragraph of the present office action. In particular, the Examiner has rejected claims 68-74 for the following reasons:

The "amino acid residues **10 to 20** of SEQ ID NO: 1,...amino acid residues **40 to 50** of SEQ ID NO: 1... amino acid residues **70 to 90** of SEQ ID NO: 1,...amino acid residues **100 to 113** of SEQ ID NO: 1 " in Claim 68 represents a departure from the specification and the claims as originally filed. The passages pointed out by applicant in the amendment filed 8/4/03 do not provide a clear support for the said specific amino acid residues.

Page 8, third full paragraph of the present office action (emphasis in the original).
Applicants respectfully disagree and traverse.

As pointed out by Applicants on page 12, line 7 of the election and preliminary amendment filed August 4, 2003, the particular amino acid sequences of claim 68 are supported by the present specification as follows:

Among highly preferred fragments in this regard are those that comprise regions of ICE LAP-6 that combine several structural features, such as several of the features set out above. In this regard, the regions defined by the residues **about 10 to about 20, about 40 to about 50, about 70 to about 90 and about 100 to about 113** of Figure 1 or the polypeptide encoded by the deposited clone, which all are characterized by amino acid compositions highly characteristic of turn-regions, hydrophilic regions, flexible-regions, surface-forming regions, and high antigenic index-regions, are especially highly preferred regions. Such regions may be comprised within a larger polypeptide or **may be by themselves a preferred fragment of the present invention**, as discussed above. It will be appreciated that the term "about" as used in this paragraph has the meaning set out above regarding fragments in general.

Page 27, lines 14-24 of the present specification (emphasis added). Thus, claims 68-74 are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Nevertheless, Applicants have amended claim 68. Accordingly,

Applicants respectfully request that rejection of claims 68-74 under 35 U.S.C. § 112, First Paragraph, be withdrawn.

VII. Rejection of Claims 27-29, 32, 35-41, 48-50, 53, 57-62, and 64-73 Under 35 U.S.C. 112, Second Paragraph

Claims 27-29, 32, 35-41, 48-50, 53, 57-62, and 64-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. *See* page 8, 5th full paragraph of the present office action. Applicants respectfully disagree and traverse.

A. Claims 27, 48, and 66

Claims 27, 48, and 66 have been rejected for the following reason:

The “fragment thereof” which is a human antibody in claims 27, 48, and 66 is ambiguous and indefinite because only antibody can be a human antibody and not antibody fragment can be a human antibody. One of ordinary skill in the art cannot appraise the metes and bound of the claimed invention.”

Page 8, 6th full paragraph of the present office action. Applicants respectfully disagree, and point out that the phrase “fragment thereof” recited in claims 27, 48, and 64 refers to an antibody fragment derived from the antibody. For example, when the recited antibody is human, then the “fragment thereof” is a fragment of a human antibody. Thus, Applicants assert that claims 27, 48, and 66 are clear and definite as written. Nevertheless, Applicants have amended claims 27, 48, and 66 to recite “...wherein the antibody or fragment thereof is human.” Accordingly, Applicants respectfully request that rejection of claims 27, 48, and 66 under 35 U.S.C. 112, second paragraph be withdrawn.

B. Claims 28 and 49 and 29, 40, 50, 62, 65, and 73

The Examiner has rejected claims 28 and 49 (directed to polyclonal antibodies) and claims 29, 40, 50, 62, 65, and 73 (directed to monoclonal antibodies) as being ambiguous and indefinite for the same reasons that claims 27, 48, and 66 were rejected as described in section A above. *See* page 8, final paragraph to page 9, 1st full paragraph. Applicants respectfully disagree, and point the Examiner to reasoning given in section A above.

Thus, Applicants assert that claims 28, 29, 40, 49, 50, 62, 65, and 73 are clear and definite as written. Nevertheless, Applicants have amended claims 28, 29, 40, 49, 50, 62, 65, and 73 by inserting the phrase “...or a fragment of a...antibody.” Accordingly, Applicants respectfully request that rejection of claims 28, 29, 40, 49, 50, 62, 65, and 73 under 35 U.S.C. 112, second paragraph be withdrawn.

C. Claims 32 and 53

The Examiner has rejected claims 32 and 53 as “...indefinite and ambiguous because hybridoma does not produce antibody fragment.” See page 9, 2nd full paragraph of the present office action. Applicants respectfully disagree, nevertheless the phrase “fragment thereof” has been deleted from claims 32 and 53, thereby obviating the Examiners rejection under 35 U.S.C. 112, second paragraph.

D. Rejection of Claims 35-39, 57-61, and 68-72

The Examiner has rejected claims 35, 57, 68, and dependent claims 36-39, 58-61, and 69-72, respectively, as indefinite and ambiguous because, “...only antibody, not antibody fragment, can be obtained from animal that has been immunized with a protein.” See page 9, 3rd full paragraph of the present office action.

As described in sections A and B above, the “fragment thereof” portion of the phrase “The antibody or fragment thereof” of claims 35, 57, and 68 refers to an antibody fragment derived from the immediately preceding “antibody.” Thus, Applicants assert that claims 35, 57, and 68 are clear and definite as written. However, Applicants have amended claims 35, 57, and 68 to insert the phrase, “...wherein the antibody has been obtained from an animal...” Accordingly, Applicants respectfully request that rejection of claims 35-39, 57-61, and 68-72 under 35 U.S.C. 112, second paragraph be withdrawn.

E. Rejection of Claim 64

Claim 64 is rejected under 35 U.S.C. 112, second paragraph. More particularly, the Examiner alleges that,

The antibody that binds to ICE-LAP 6 protein in claim 64
"is encoded by a polynucleotide encoding amino acids 1 to
416 of SEQ ID NO:1 operably associated with a regulatory
sequence that controls the expression of said polynucleotide

is ambiguous and indefinite because if the antibody or fragment thereof binds to a protein consisting of 1 to 416 of SEQ ID NO: 1, then the claim should recite that protein.

Page 9, 4th full paragraph of the present specification. Applicants respectfully disagree. The Examiner alleges that "...if the antibody or fragment thereof binds to a protein consisting of 1 to 416 of SEQ ID NO:1, then the claim should recite that protein." Claim 64 does encompass antibodies that bind a polypeptide purified from a cell culture, wherein said polypeptide corresponds to amino acids 1 to 416 of SEQ ID NO:1.

However, one of ordinary skill in the art would recognize that claim 64 also encompasses, for example, antibodies that bind polypeptides purified from cells containing the polynucleotide encoding amino acids 1 to 416 of SEQ ID NO:1, wherein said polypeptides are subject to post-translational modification. *See* page 13, line 15 to page 15, line 24 of the present specification.

Therefore, claim 64 is definite and clear as written because one of skill in the art would understand claim 64 to encompass antibodies against any form of the ICE-LAP 6 polypeptide which can be purified from a cell, i.e., ICE LAP-6 polypeptide corresponding to amino acids 1 to 416 of SEQ ID NO:1, and ICE LAP-6 polypeptide that has been subject to host cell dependent post-translational modification. Accordingly, Applicants respectfully request that rejection of claim 64 under 35 U.S.C. 112, second paragraph, be withdrawn.

Conclusion

In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance. An early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicant would expedite allowance of this application.

Finally, if there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: 19 February 2004



Lin J. Hymel (Reg. No. 45,414)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
Telephone: (301) 241-6015
Facsimile: (301) 309-8439

KKH/LJH/ZSS/vr